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8  
9 IN THE UNITED STATES DISTRICT COURT  
10 FOR THE CENTRAL DISTRICT OF CALIFORNIA  
11 WESTERN DIVISION

12  
13 **UNITED STATES OF AMERICA;  
THE STATES OF CALIFORNIA,  
14 GEORGIA, ILLINOIS, INDIANA,  
MICHIGAN, NEVADA, NEW  
15 JERSEY, NEW MEXICO, NEW  
YORK, RHODE ISLAND; and THE  
16 COMMONWEALTH OF  
MASSACHUSETTS, ex rel. JOHN  
17 M. LOCKWOOD, MD,**

18 Plaintiffs,

19 v.

20 **SANOFI US SERVICES INC.; and  
21 SANOFI-AVENTIS U.S. LLC,**

22 Defendants.  
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No. 2:23-cv-05490-SVW (MRWx)

**STATEMENT OF INTEREST BY  
THE STATES REGARDING  
DEFENDANTS' MOTION TO  
DISMISS RELATOR'S FIRST  
AMENDED COMPLAINT (ECF  
NO. 53) AND RELATOR'S  
MOTION FOR VOLUNTARY  
DISMISSAL WITHOUT  
PREJUDICE (ECF NO. 55)**

1 The States of California, Georgia, Illinois, Indiana, Michigan, Nevada, New  
2 Jersey, New Mexico, New York, Rhode Island, and the Commonwealth of  
3 Massachusetts (collectively, the “States”) file this Statement of Interest regarding  
4 Defendants Sanofi US Services Inc. and Sanofi-Aventis U.S. LLC’s (collectively,  
5 “Sanofi”) Motion to Dismiss Relator’s First Amended Complaint (ECF No. 53) and  
6 Relator John M. Lockwood, MD’s Motion for Voluntary Dismissal Without  
7 Prejudice (ECF No. 55). In light of the current posture of this case and the nature of  
8 the pending issues before the Court on Sanofi’s Motion to Dismiss, the States  
9 respectfully submit the following in support of obtaining a ruling on the merits as to  
10 Sanofi’s Motion to Dismiss before Relator’s Motion for Voluntary Dismissal  
11 Without Prejudice is addressed by the Court, the United States, and the States:  
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13 **Brief Procedural History of Relator’s *Qui Tam* Action**

14 On July 10, 2023, Relator filed his Original *qui tam* Complaint (ECF No. 1)  
15 alleging violations of the federal False Claims Act (“Federal FCA”), 31 U.S.C. §§  
16 3729-3733, and analogous false claims statutes of the States<sup>1</sup>. The Federal FCA and  
17 the States’ false claims statutes provide that a private person, known as a “relator,”  
18 may bring a civil action on behalf of the United States and the States. 31 U.S.C. §  
19 3730(b)(1); *see, e.g.*, Cal. Gov’t Code § 12652(c)(1). The Relator’s Original  
20 Complaint alleging fraud concerning the nationwide Medicaid Drug Rebate  
21 Program, 42 U.S.C. § 1396r-8, prompted a joint investigation by the United States  
22 and the States’ Medicaid Fraud Control Units (“MFCUs”). 31 U.S.C. § 3730(a).  
23 Under federal statute, the mission of each MFCU is to investigate and prosecute  
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25 <sup>1</sup> California False Claims Act, Cal. Gov’t Code §§ 12650-12656; Georgia False Medicaid Claims  
26 Act, Ga. Code Ann. §§ 49-4-168 to -168.6; Illinois False Claims Act, 740 Ill. Comp. Stat. 175/3;  
27 Indiana Medicaid False Claims and Whistleblower Protection Act, Ind. Code §§ 5-11-5.7-1 to -  
28 18; Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, §§ 5A-5O; Michigan Medicaid  
False Claims Act, Mich. Comp. Laws §§ 400.601-.615; Nevada False Claims Act, Nev. Rev. Stat.  
§§ 357.010-.250; New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 to -18; New Mexico  
Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 to -15; New York False Claims Act,  
N.Y. State Fin. Law §§ 187-194; Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 to -9.

1 fraud against their state's Medicaid program pursuant to state law. 42 U.S.C. §  
2 1396b(q). The Medicaid program, which is jointly funded by the federal  
3 government and each State, provides free or low-cost health coverage to millions of  
4 the most vulnerable Americans, including low-income individuals, families and  
5 children, pregnant women, the elderly, and people with disabilities. 42 U.S.C. §  
6 1396b. The Medicaid Drug Rebate Program requires drug manufacturers to pay  
7 unit-based rebates to the States for the drugs that are purchased for each State's  
8 Medicaid beneficiaries. 42 U.S.C. § 1396r-8(a). These rebates are calculated using  
9 the drug-pricing data reported by the manufacturers. 42 U.S.C. § 1396r-8(b)(3).

10 After an initial six-month seal, under which the States and United States  
11 (collectively, the "Governments") were conducting their joint investigation, the  
12 Court denied the Governments' request for further extension of the seal and  
13 intervention period. ECF No. 24. As the Governments' joint investigation was  
14 ongoing and they lacked sufficient information upon which to decide whether to  
15 intervene in the *qui tam* action, the United States and States filed their respective  
16 notices on February 21, 2024, to inform the Court that they were not intervening in  
17 the case at the time of filing, but would continue their joint investigation. ECF Nos.  
18 25, 27; *see also* ECF Nos. 26, 28 (Orders Re: ECF Nos. 25, 27).

19 Pursuant to the Federal FCA and the States' false claims statutes, the Relator  
20 has proceeded in the action in the name of the Governments while the  
21 Governments' joint investigation has continued. 31 U.S.C. § 3730(c)(3); *see, e.g.*,  
22 Cal. Gov't Code § 12652(c)(5).

23 The Original Complaint was subsequently unsealed and served on Sanofi.  
24 ECF Nos. 26, 28, 36, 37. Sanofi filed a motion to dismiss as to the Original  
25 Complaint on May 6, 2024. ECF No. 46. Relator filed the operative First Amended  
26 Complaint (ECF No. 52) on May 28, 2024, which was followed by Sanofi's  
27 pending Motion to Dismiss Relator's First Amended Complaint with prejudice on  
28 June 10, 2024 (ECF No. 53).

Sanofi's Motion to Dismiss the First Amended Complaint is based on the public disclosure bars under the federal False Claims Act ("Federal FCA"), 31 U.S.C. § 3730(e)(4)(A), and the States' respective false claims statutes,<sup>2</sup> as well as Federal Rules of Civil Procedure 12(b)(6) and 9(b) on the grounds that Relator failed to adequately plead falsity and scienter. ECF No. 53. Relator filed his opposition on July 8, 2024. ECF No. 56. Sanofi's Motion to Dismiss is set for hearing on August 5, 2024.

On July 1, 2024, Relator John M. Lockwood, MD filed a Motion for Voluntary Dismissal Without Prejudice. ECF No. 55. Relator's Motion for Voluntary Dismissal was scheduled for hearing on July 29, 2024, in advance of Sanofi's previously filed Motion to Dismiss.

**The States Have an Ongoing Interest in the Matters at Issue in the Motion to Dismiss**

In light of the unsealed status of the case, the import to the States of the issues raised by Relator's First Amended Complaint and Sanofi's Motion to Dismiss regarding the Medicaid Drug Rebate Program, and the advanced stage of the briefing on the Motion to Dismiss with the filing of Relator's opposition on July 8, 2024, the States believe a ruling on the merits of Sanofi's Motion to Dismiss will better inform the States in their decisions of whether to consent to or object to Relator's Motion for Voluntary Dismissal.

As the States have yet to make their intervention decisions and have ongoing investigations into the allegations contained in the Relator's *qui tam* Complaint, the States retain their interest in this matter. Actions brought under the *qui tam* provisions of the States' false claim statutes are brought for the benefit of the States

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<sup>2</sup> Cal. Gov't Code § 12652(d)(3)(A)-(C); Ga. Code Ann. § 49-4-168.2(l); 740 Ill. Comp. Stat. Ann. 175/4(e)(4)(A)-(B); Ind. Code Ann. § 5-11-5.7-7(e)-(f); Mich. Comp. Laws Ann. § 400.610a(13); Nev. Rev. Stat. Ann. § 357.100; N.J. Stat. Ann. § 2A:32C-9(c); N.M. Stat. Ann. § 27-14-10; N.Y. State Fin. Law § 190(9)(b); 9 R.I. Gen. Laws Ann. § 9-1.1-4(e)(4); Mass. Gen. Laws Ann. ch. 12, § 5G(c).

1 themselves, and are litigated by the relator in the name of the States, unless those  
2 States intervene. Cal. Gov't Code § 12652(c); Ga. Code Ann. § 49-4-168.2(b)-(c),  
3 (f); 740 Ill. Comp. Stat. Ann. 175/4(b)-(c); Ind. Code Ann. § 5-11-5.7-4; Mich.  
4 Comp. Laws Ann. § 400.610a; Nev. Rev. Stat. Ann. § 357.080; N.J. Stat. Ann. §  
5 2A:32C-5(b); N.M. Stat. Ann. §§ 27-14-7, 27-14-8; N.Y. State Fin. Law § 190(2);  
6 9 R.I. Gen. Laws Ann. § 9-1.1-4(b)-(c); Mass. Gen. Laws Ann. ch. 12, § 5C(2)-(4).  
7 Irrespective of State intervention, each of the States' false claims statutes provide  
8 that any recovery of civil penalties and damages are on behalf of the State. Cal.  
9 Gov't Code § 12652(g); Ga. Code Ann. § 49-4-168.2(i); 740 Ill. Comp. Stat. Ann.  
10 175/4(d); Ind. Code Ann. § 5-11-5.7-6; Mich. Comp. Laws Ann. § 400.610a; Nev.  
11 Rev. Stat. Ann. § 357.210; N.J. Stat. Ann. § 2A:32C-7; N.M. Stat. Ann. § 27-14-9;  
12 N.Y. State Fin. Law § 190(6); 9 R.I. Gen. Laws Ann. § 9-1.1-4(d); Mass. Gen.  
13 Laws Ann. ch. 12, §§ 5F, 5H. The States' false claims statutes protect the States'  
14 interests in *qui tam* actions for the duration of the litigation through provisions that,  
15 for example, safeguard the States' ability to intervene in an action after an initial  
16 declination if the interests of the State in recovering the funds at issue are not being  
17 adequately represented by the relator, as well as provisions that require State  
18 consent for dismissal.

19 Although Relator has proceeded in the litigation in the name of the  
20 Governments, as acknowledged in Relator's Motion for Voluntary Dismissal and as  
21 set forth in the relevant portions of the States' statutes, the Federal FCA and the  
22 States' false claims statutes prohibit the dismissal of claims brought by a *qui tam*  
23 relator under those statutes in the absence of the respective consent of the United  
24 States and the States. 31 U.S.C. § 3730(b)(1); Cal. Gov't Code § 12652(c)(1); Ga.  
25 Code Ann. § 49-4-168.2(b); 740 Ill. Comp. Stat. Ann. 175/4(b)(1); Ind. Code Ann.  
26 § 5-11-5.7-4(b)(1); Mich. Comp. Laws Ann. § 400.610a(1); Nev. Rev. Stat. Ann. §  
27 357.080(1); N.J. Stat. Ann. § 2A:32C-5(c); N.M. Stat. Ann. § 27-14-7(B); N.Y.  
28 State Fin. Law § 190(5)(a); 9 R.I. Gen. Laws Ann. § 9-1.1-4(b)(1); Mass. Gen.

1 Laws Ann. ch. 12, § 5C(2); *see also* ECF No. 26 at ¶ 6 (“Should the Relator or  
2 defendants propose that this action be dismissed, settled, or otherwise discontinued,  
3 the parties shall provide the United States with notice of the same and the Court  
4 will provide the United States with an opportunity to be heard before ruling or  
5 granting its approval”); ECF No. 27 at 4 (“The States therefore request that, should  
6 there be a proposal that this action be dismissed, settled, or otherwise discontinued,  
7 the Court require the written consent of the States in advance of the Court’s  
8 ruling”); ECF No. 55-1 at 1 (“Pursuant to the federal False Claims Act and the false  
9 claims acts of the plaintiff states, however, the consent of this Court and the federal  
10 and state governments is required before the action may be dismissed”).

11 Relator’s Motion for Voluntary Dismissal, filed while Sanofi’s Motion to  
12 Dismiss was pending, is scheduled to be heard before Sanofi’s Motion to Dismiss.  
13 As a result, the States run the risk of making premature decisions that may directly  
14 and negatively affect the States’ interest in protecting their Medicaid programs if  
15 required to consent or object to voluntary dismissal ahead of a ruling on the merits  
16 of Sanofi’s Motion to Dismiss.

17 In its Motion to Dismiss, Sanofi argues that the First Amended Complaint  
18 must be dismissed because this Court lacks subject-matter jurisdiction under the  
19 public disclosure bar of the Federal FCA and the States’ false claims statutes. ECF  
20 No. 53-1 at 17-28 (citing 31 U.S.C. § 3730(e)(4)(A) and referencing ECF No. 46-1  
21 n. 6 for authorities cited). According to Sanofi, the material elements of Relator’s  
22 claims were in the public domain before Relator filed this action and Relator has  
23 not shown and cannot show that he qualifies as an original source. ECF 53-1 at 17-  
24 28.

25 However, the States oppose dismissal on public disclosure grounds. The States  
26 therefore submitted their Notice of States’ Opposition to Dismissal of State Law  
27 Claims Based on the Public Disclosure Bar on July 16, 2024, exercising their rights  
28 under the applicable provisions of their respective State false claims statutes to

1 object to dismissal, on public disclosure grounds, of the State law claims in Relator  
2 John M. Lockwood, MD's First Amended Complaint. [ECF No. 58].

3       Narrowed by the States' opposition to dismissal based on the public disclosure  
4 bar, the remaining issues before the Court are Sanofi's assertions that Relator has  
5 failed to adequately plead falsity and scienter. ECF 53-1 at 10-16, 27. As with the  
6 Federal FCA, the States' false claims statutes provide, in pertinent part, that any  
7 entity that (1) knowingly presents, or causes to be presented, a false or fraudulent  
8 claim for payment or approval; (2) knowingly makes, uses, or causes to be made or  
9 used, a false record or statement material to a false or fraudulent claim; or (3) is a  
10 beneficiary of an inadvertent submission of a false claim, subsequently discovers  
11 the falsity of the claim, and fails to disclose the false claim to the State within a  
12 reasonable time after discovery, is liable to the State for damages and penalties.  
13 Cal. Gov't Code § 12651(a); Ga. Code Ann. § 49-4-168.1(a); 740 Ill. Comp. Stat.  
14 Ann. 175/3(a); Ind. Code Ann. § 5-11-5.7-2(a); Mich. Comp. Laws Ann. § 400.607;  
15 Nev. Rev. Stat. Ann. § 357.040(1); N.J. Stat. Ann. § 2A:32C-3; N.M. Stat. Ann. §  
16 27-14-4; N.Y. State Fin. Law § 189(1); 9 R.I. Gen. Laws Ann. § 9-1.1-3(a); Mass.  
17 Gen. Laws Ann. ch. 12, § 5B(a). Proof that an entity acted "knowingly" includes  
18 proof that the entity, with respect to the relevant information (1) has actual  
19 knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity  
20 of the information; or (3) acts in reckless disregard of the truth or falsity of the  
21 information. Cal. Gov't Code § 12650(b)(3); Ga. Code Ann. § 49-4-168(2); 740 Ill.  
22 Comp. Stat. Ann. 175/3(b)(1); Ind. Code Ann. § 5-11-5.7-1(b)(4); Mich. Comp.  
23 Laws Ann. § 400.602(f); Nev. Rev. Stat. Ann. § 357.040(3); N.J. Stat. Ann. §  
24 2A:32C-2; N.Y. State Fin. Law § 188(3); 9 R.I. Gen. Laws Ann. § 9-1.1-3(b)(2);  
25 Mass. Gen. Laws Ann. ch. 12, § 5A.

26       Two core elements under the States' false claims statutes — falsity and  
27 scienter — are the subject of the pending Motion to Dismiss, which is in an  
28 advanced stage of the briefing. Due to the significance of these issues and the



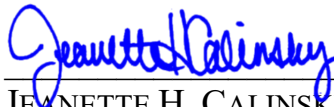
1 nature of the allegations of Medicaid drug rebate fraud set forth in the Relator's  
2 Complaint, the Court's ruling on the Motion to Dismiss is pertinent to the States'  
3 ongoing evaluation of the case and their positions on the Relator's request for  
4 voluntary dismissal.

5 The States therefore believe any decisions on Relator's Motion for Voluntary  
6 Dismissal prior to ruling on the Motion to Dismiss would be premature and deprive  
7 the States of their interests in ensuring that the allegations are adequately  
8 investigated and prosecuted. To that end, the States respectfully request the Court  
9 rule on Sanofi's Motion to Dismiss before Relator's Motion for Voluntary  
10 Dismissal is addressed.

11  
12 Dated: July 16, 2024

Respectfully submitted,

13 ROB BONTA  
14 Attorney General of California

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16 JEANETTE H. CALINSKY  
17 Deputy Attorney General  
18 *Attorneys for Plaintiff State of*  
19 *California and on Behalf of the*  
20 *States*



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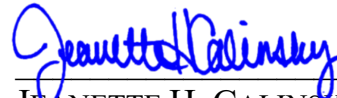
Attestation

I hereby attest that the other signatories listed, on whose behalf this filing is submitted, concur in its content and have authorized its filing.

Dated: July 16, 2024

Respectfully submitted,

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